K020440
p1/2

Section E

510(K) SUMMARY

Submitted by:
Siemens Medical Solutions USA, Inc.
186 Wood Avenue South
Iselin, NJ 08830

DEC 0 3 2002

This 510(k) summary of safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR § 807.92.

1. Contact Person

Sandra Robinson
Technical Specialist
Phone (732) 321-3243 Fax: (732) 321-4841

2. Device Name and Classification

Trade Name:	AXIOM Sensis
Internal name of R&D:	NEWCOR
Classification name:	Programmable diagnostic computer
Classification Panel	21 CFR § 870.1425
Classification Number	DQK
Classification class	II

3. Intended Use

The AXIOM Sensis system is intended for use as a diagnostic and administrative tool supporting hemodynamic cardiac catheterizations and/or intracardiac electrophysiology studies. The system is equipped by modules, enabling various configurations ranging from a stand-alone acquisition unit with limited administrative functionality to multiunit installations with a common database and satellite workstations accessing the data using the administrative tools. Many of the components used in AXIOM Sensis are either commercially available with current Siemens systems or include minor modifications to existing components.

4. Substantial Equivalence

AXIOM Sensis system is substantially equivalent to the following legally market devices:

GE PRUCKA CARDIOLAB® 7000	K993414, cleared on April 7, 2000
Siemens CATHCOR LX Desktop	K002137, cleared on Oct 5, 2000
Siemens EPCOR option	K930786, cleared on Sept 26, 1994
Nonin Neonatal/Adult Vital Sign Monitor (SpO2)	K982776, cleared on Aug 9, 1998
SunTech Oscar II BP Monitor (NIBP)	K003004, cleared on Oct 25, 2000
SC9000 Infinity Monitor (HR & CO)	K980882, cleared on June 5, 1998

Information that substantiates this claim of equivalence is provided throughout this 510(k) submission and specific equivalence information is provided in section M.

5. Device Description

AXIOM Sensis is a multi-channel computer-based stationary system for the measurement, display, and printout of biophysiological events. Hemodynamic and electrophysiological signals such as intracardiac pressure, ECG signals, and intracardiac electrograms (ICEG) are measured and displayed by the system. AXIOM Sensis software provides the ability to monitor and assess invasive blood pressure, ECG signals, and optionally intracardiac electrograms (ICEG). With the AXIOM Sensis system the user can perform a number of calculations based on the input signals and other hemodynamic parameter values entered by the user.

K020440
p 2/2

6. **Summary of Technological Characteristics of the Principal Device as Compared with the Predicate Device**

AXIOM Sensis goes one-step beyond the currently available systems to create modular units with component commonality, streamlined user interface and use, and performance and reliability improvement.

Technological Characteristics:

The Axiom Sensis described supports a subset of DICOM and HL 7 communication interfaces, communication with Siemens X-ray systems via HICOR and Axiom Artis communication protocols, and communication of parameter data from Medtronic Model 4803 Atakr® II RF Power Generator, Boston Scientific EP Technologies EPT-100 TC and Stockert EP-Shuttle ablation devices.

AXIOM Sensis is based on the Syngo platform, which received FDA 510(k) clearance K010938 on June 25, 2001.

7. **General Safety and Effectiveness Concerns**

Instructions for use are included within the device labelling and the information provided will enable the trained healthcare professional to operate the device in a safe and efficacious manner. Furthermore the operators are health care professionals familiar with and responsible for the examinations to be performed. To minimize electrical, mechanical and radiation hazards, Siemens adheres to recognized and established industry practice, and all equipment is subject to final performance testing.

8. **Substantial Equivalence**

In the opinion of Siemens Medical Systems, Inc., the hardware and software documentation and the substantial equivalence comparison matrix proves that the AXIOM Sensis Electrophysiological and Hemodynamic Recording System is substantially equivalent to the Siemens Medical Systems, Inc. predicate Cathcor LX Desktop System, with EPCOR option and the General Electric Inc. Prucka Cardiolab 7000 system.
AXIOM Sensis is substantial equivalent on parameter level with Nonin Neonatal/Adult Vital Sign Monitor (SpO2), SunTech Oscar II BP Monitor (NIBP) and Siemens SC9000 Infinity Monitor (HR & CO).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 0 3 2002

Siemens Medical Systems, Inc.
c/o Ms. Kathleen Rutherford
Manager, Regulatory Submissions
186 Wood Avenue South
Iselin, NJ 08830

Re: K020440
Trade Name: AXIOM Sensis
Regulation Number: 21 CFR 870.1425
Regulation Name: Programmable Diagnostic Computer
Regulatory Class: Class II (two)
Product Code: DQK
Dated: Undated
Received: September 5, 2002

Dear Ms. Rutherford:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4646. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known):

Device Name: AXIOM Sensis

Indications For Use:
The AXIOM Sensis system is intended to be used as a diagnostic and administrative tool supporting hemodynamic cardiac catheterizations and/or intracardiac electrophysiology studies. The system is equipped by modules, enabling various configurations ranging from a stand-alone acquisition unit with limited administrative functionality to multiunit installations with a common database and satellite workstations accessing the data using the administrative tools.

The AXIOM Sensis system has functions for:

1. External communication via the DICOM interface by using Siemens Medical Platform *syngo* ™ and AXIOM Sensis VC00A DICOM Conformance Statement
2. External Communication via the HL7 interface by using AXIOM Sensis Interface description HL7 Interface.
3. Local communication by using the Siemens HICOR interface
4. Local communication by using the Siemens AXIOM Artis FC/BC interface
5. Local communication with Medtronic Model 4803, Atakr® II RF Power Generator, Boston Scientific EP Technologies EPT-100 TC, and Stockert EP-Shuttle Ablator devices

The device is intended to be used on either or both of the following populations:

1. Adult and pediatric populations requiring intracardiac electrophysiology examinations, typically when the patient is suffering from cardiac arrhythmias.
2. Adult and pediatric populations requiring intracardiac hemodynamic examinations, typically when the patient has a heart disease resulting in insufficient hemodynamic functionality.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NECESSARY)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use_X___ OR Over-The-Counter Use_____
(Per 21 CFR 801.